

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form	: Substance
Trade name	: PRILOCAINE HCL
IUPAC name	: N-(2-methylphenyl)-2-(propylamino)-Propanamide hydrochloride
CAS-No.	: 1786-81-8
Product code	: 94270
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C ₁₃ H ₂₀ N ₂ O.HCl
Synonyms	: Propitocaine hydrochloride, Propanamide, N-(2-methylphenyl)-2-(propylamino)- (9Cl) hydrochloride ; 2-Methyl-alpha-propylaminopropionanilide hydrochloride ; 2-Methyl-alpha-propylaminopropionanilide hydrochloride
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: CCCNC(C)C(=O)NC1=CC=CC=C1C.Cl

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Main use category	: Industrial use,Professional use,Medicinal use,API
Industrial/Professional use spec	: Laboratory activities Active Ingredient for Medicinal / Pharmaceutical Use For professional use only Industrial
Use of the substance/mixture	: Anesthetics, Local Anesthetics. Prilocaine binds to the intracellular surface of sodium channels which blocks the subsequent influx of sodium into the cell. Action potential propagation and never function is, therefore, prevented. This block is reversible and when the drug diffuses away from the cell, sodium channel function is restored and nerve propagation returns.
Function or use category	: Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet**Head office**

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hse@moehs.es - www.moehs.com

Manufacturer

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Manufacturer

BENECHIM S.P.R.L.
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B-7860 Lessines - Belgium
T + 32 68 33 49 13

1.4. Emergency telephone number

Emergency number : +34 93 586 05 20
(9:00 - 17:00)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Hazardous to the aquatic environment — Chronic Hazard, Category 4	H413
Full text of H statements : see section 16	

Adverse physicochemical, human health and environmental effects

Harmful if swallowed.

PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H413 - May cause long lasting harmful effects to aquatic life.

Precautionary statements (CLP) :

P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear eye protection, protective gloves, face protection, protective clothing.
P301+P312 - IF SWALLOWED: Call a doctor if you feel unwell.
P330 - Rinse mouth.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P273 - Avoid release to the environment.
P501 - Dispose of contents/container to an approved waste disposal plant.

2.3. Other hazards

Other hazards not contributing to the classification : Dust may form explosive mixture in air.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
PRILOCAINE HCL	(CAS-No.) 1786-81-8	100

Full text of R- and H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow affected person to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact : Wash with plenty of water/.... Take off contaminated clothing. Wash contaminated clothing before reuse.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth out with water. Do not induce vomiting. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : If you feel unwell, seek medical advice.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : Harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Toxic fumes may be released.

PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

5.3. Advice for firefighters

Precautionary measures fire	: Stop leak if safe to do so.
Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment	: Breathing equipment.
Emergency procedures	: Evacuate unnecessary personnel. Avoid breathing dust, mist, vapours.
Measures in case of dust release	: Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area. Shovel or sweep up and put in a closed container for disposal. Stop leak if safe to do so.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust, mist, vapours.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling. Separate working clothes from town clothes. Launder separately.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep away from ignition sources. Keep container closed when not in use. Keep container tightly closed.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage temperature	: <= 25 °C
Storage area	: Store in a well-ventilated place. Store away from heat.

7.3. Specific end use(s)

Pharmaceuticals.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional information : MOEHS occupational exposure band : 2 (0.1-1 mg/m3)

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Local exhaust or breathing protection. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Breathing equipment.

Personal protective equipment:

Avoid all unnecessary exposure. Gloves. Safety glasses. Dust/aerosol mask with filter type P3.

Hand protection:

Wear protective gloves.

Type	Material	Standard
Disposable gloves	Latex, Polyvinylalcohol (PVA), Polyvinylchloride (PVC), Natural rubber	EN 374

Eye protection:

Chemical goggles or safety glasses

PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear appropriate mask

Device	Filter type	Condition	Standard
Dust mask	Type P3	Dust protection	EN 143

Personal protective equipment symbol(s):



Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Molecular mass	: 256.81 g/mol
Colour	: white.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 4.5 - 6.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 36 - 39 °C [prilocaine base]
Freezing point	: No data available
Boiling point	: 361.6±25.0 °C at 760 mmHg [predicted by ACD/Labs] ; 378.65 °C (Adapted Stein & Brown method - MPBPWIN v1.42)[prilocaine base]
Flash point	: 134.3±23.3 °C [predicted by ACD/Labs]
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: 2.13E-005 mmHg (Modified Grain method) According MPBPWIN v1.42
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1.0±0.1 g/cm ³ [Predicted by ACD/Labs] [Prilocaine base]
Solubility	: Water: 541 mg/l [25°C; Prilocaine base]
Log Pow	: 2.11 According United States National Library of Medicine (CHEMIDPLUS) [Prilocaine base] ; 1.87 According ALOGPS [Prilocaine base]
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Oral: Harmful if swallowed.

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

PRILOCAINE HCL (1786-81-8)

LD50 oral rat	300 - 2000 mg/kg (OECD Guideline 423) The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.
LD50, subcutaneous, mouse	519 mg/kg ((Nippon Yakurigaku Zasshi. Japanese Journal of Pharmacology. Vol. 61, Pg.))
LD50, intraperitoneal, mouse	231 mg/kg ((Nippon Yakurigaku Zasshi. Japanese Journal of Pharmacology. Vol. 61, Pg.))
LD50, intravenous, mouse	59.9 mg/kg ((Nippon Yakurigaku Zasshi. Japanese Journal of Pharmacology. Vol. 61, Pg.))

Skin corrosion/irritation : Causes skin irritation.

pH: 4.5 - 6.5

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Causes serious eye irritation.

pH: 4.5 - 6.5

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

Germ cell mutagenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Additional information : Based on available data, the classification criteria are not met

Reproductive toxicity : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-single exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

STOT-repeated exposure : Not classified

Additional information : Based on available data, the classification criteria are not met

Aspiration hazard : Not classified

Additional information : Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms : Harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - water : May cause long lasting harmful effects to aquatic life.

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : May cause long lasting harmful effects to aquatic life.

PRILOCAINE HCL (1786-81-8)

LC50 fish 1	188 mg/l
EC50 Daphnia 1	33.1 mg/l

12.2. Persistence and degradability

PRILOCAINE HCL (1786-81-8)

Persistence and degradability	May cause long-term adverse effects in the environment. Minimally biodegradable % biodegradation < 10 % CO2 formation relative to the theoretical value (28 d) (OECD 301B; ISO 9439; 92/69/EEC, C.4-C) (aerobic, activated sludge, domestic).
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PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

12.3. Bioaccumulative potential

PRILOCAINE HCL (1786-81-8)

BCF fish 1	1 [pH 5.5; Predicted by ACD/Labs]
Log Pow	2.11 According United States NATIONAL Lybrary of Medicine (CHEMIDPLUS) [Prilocaine base] ; 1.87 According ALOGPS [Prilocaine base]
Bioaccumulative potential	Not established.

12.4. Mobility in soil

PRILOCAINE HCL (1786-81-8)

Log Koc	1.79 [pH 5.5; Predicted by ACD/Labs]
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12.5. Results of PBT and vPvB assessment

PRILOCAINE HCL (1786-81-8)

vPvB: not relevant – no registration required

12.6. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

PRILOCAINE HCL is not on the REACH Candidate List

PRILOCAINE HCL is not on the REACH Annex XIV List

15.1.2. National regulations

Germany

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
SDS	Safety Data Sheet
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose

PRILOCAINE HCL

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

LOAEL	Lowest Observed Adverse Effect Level
vPvB	Very Persistent and Very Bioaccumulative
NOAEL	No-Observed Adverse Effect Level
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H413	May cause long lasting harmful effects to aquatic life.
R22	Harmful if swallowed
R36	Irritating to eyes
R38	Irritating to skin
R53	May cause long-term adverse effects in the aquatic environment
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.